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Mark Geil
Georgia State University, mgeil@gsu.edu

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Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics

Mark D. Geil, PhD
Department of Kinesiology and Health, Georgia State University, Atlanta, GA

Abstract—Evidence-based practice combines a practitioner's training and experience with evidence established through scientific research. Fundamental to the evidence-based process for prosthetics and orthotics is the ongoing availability of clinically applicable research on relevant conditions, components, and patient populations. In the past, research has been successfully applied to practice, sometimes producing substantial changes. Examples include clinically applicable research that has assessed treatment effectiveness, altered clinical patient interaction, led to the development of new components and technologies, and challenged or changed long-standing clinical opinion. Despite past successes, obstacles remain in the application of research to practice. Practitioners have stated a desire for research and have identified a list of research needs but lack the training or resources necessary to conduct the research. A gulf also exists between the perceived research needs and the clinically applicable research that is being produced, possibly because of the broad nature of those needs.

Key words: clinical decision-making, clinically applicable research, evidence-based practice, literature review, orthotics, patient care, prosthetics, rehabilitation, research, research needs.

INTRODUCTION

Evidence-based practice (EBP) seeks to inform clinical decision-making by combining a practitioner's training and experience with evidence established through scientific research. Cordell and Chisolm called EBP "one of the most significant paradigm shifts and conceptual advances in facilitating the incorporation of medical innovation into practice" [1]. Almost interchangeably called evidence-based medicine or EBP, this relatively recent area of emphasis in prosthetics and orthotics (P&O) has become the subject of meeting symposia and full-day workshops. Its arrival from larger healthcare circles to P&O has raised questions about the overall quality of evidence in P&O and the applicability of that evidence to everyday clinical practice.

Sackett et al. define EBP as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients," noting that EBP should integrate "individual clinical expertise with the best available external clinical evidence from systematic research" [2]. EBP is applied to the care of each patient but relies on the collective body of external evidence. The practitioner seeking to apply EBP therefore faces a dilemma: if the strongest evidence is related to an individual patient's needs in only an ancillary way and weaker but more relevant evidence is available, which should be used to inform the treatment plan for that patient? This question begs others concerning the strength of the evidence and types of research and the relevancy and applicability of the research in P&O. As awareness of

Abbreviations: CAT-CAM = contoured adducted trochanteric-controlled alignment method, EBP = evidence-based practice, NIH = National Institutes of Health, P&O = prosthetics and orthotics.

Address all correspondence to Mark D. Geil, PhD; Department of Kinesiology and Health, Georgia State University, PO Box 3975, Atlanta, GA 30302; 404-413-8379; fax: 404-413-8053. Email: mgeil@gsu.edu
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EBP in P&O grows, a spotlight will be focused on current and future research to determine where gaps exist and where future efforts should be placed.

NATURE OF RESEARCH SUITABLE FOR JUSTIFYING PATIENT CARE

In most disciplines, P&O notwithstanding, research falls on a continuum from basic to applied, depending primarily on its motivation: either to expand a foundational base of knowledge (basic) or to solve a specific practical problem (applied). The "width" of that continuum is substantially greater in other medical disciplines than it is in P&O. For example, the same topic in pharmacological research might include a basic study of an endocrine system feedback loop and an applied study of time until alleviation of symptoms. In P&O, research that might be considered basic often has almost direct clinical application. For example, research on roll-over shape of the foot seeks to understand a basic attribute of human gait but has direct application in several areas, including prosthetic alignment [3]. In other instances, the typically plentiful applied research in P&O relies on basic research from other disciplines if it relies on basic research at all. While this phenomenon is partly due to the relative youth of sophisticated P&O research, the applied nature of the field also lends itself to applied research. It does not typically make sense to test a novel orthotic intervention on a series of animal models before reaching the point of human subject testing. Basic work is needed to assess material properties, response to stress and fatigue, and force and pressure patterns, but this work is typically done by the inventors and manufacturer of the component and is rarely published. Consequently, the first research article to appear concerning a new orthosis might be an applied study of a few human subjects using the device.

This lack of basic science germane to P&O affects EBP in multiple ways. First, it undoubtedly adds to the perception that the overall body of evidence is weak. On the other hand, because applied research produces conclusions that are directly relevant to patient care, it can be more easily implemented in EBP.

Within any body of research, several types of studies exist. As the need for an impartial understanding of the relative strength and value of different types of evidence has grown, so has the ranking of study designs. Hierarchies have emerged that are designed to grade the quality of evidence for a particular topic, or even a particular discipline. Lohr assessed 121 literature grading systems [4] and settled on 8 systems fitting a priori standards suitable for rating overall strength of evidence. Systems have been developed that are discipline-specific [5] and country-specific [6], while organizations such as the Cochrane Collaboration seek to conduct reviews for a variety of health-care issues based on broad criteria. A Cochrane review on prosthetic foot-ankle mechanisms was first published in 2004 [7]. P&O-specific literature assessments have also been conducted as part of a series of State of the Science Conferences sponsored by the American Academy of Orthotists and Prosthetists [8–12]. The majority of these systematic reviews are based on a hierarchy of study designs with randomized controlled trials at the top, recognized as most important, and individual opinion at the bottom, the lowest level of evidence. Judging by this approach, most decision-making in medicine is supported by weak evidence. A committee of the U.S. Institute of Medicine has noted that only 4 percent of medical services have strength of evidence near the top of the scale, while more than half have very weak or no evidence [13]. Judged against these low overall standards, P&O research would seem bleak, given the dearth of randomized controlled trials, low numbers of subjects, difficulties in blinding subjects, variability in subject populations, threats to validity [14], and a host of other challenges. Many systematic reviews of P&O research fail to recognize that many of the study designs representing the "strongest evidence" present serious problems when applied to P&O. Randomized controlled trials involve random assignment of subjects to control or intervention groups, with double and sometimes triple blinding of subjects and researchers to the groups and the type of interventions. Because P&O components are external and widely variable in appearance and function and because they are only suitable for certain individuals, randomized controlled trials are often impossible for component studies.

Despite these challenges, the individual practitioner making a decision for a specific patient should recognize that scientific evidence can very often be found to guide or justify a course of treatment. If EBP is viewed in the context of combining personal expertise with the best available evidence to inform and justify the care of individual patients, then hierarchies rating strength of evidence across multiple disciplines become less important. Application of evidence for the justification of treatment of an individual patient is not necessarily a complicated process. Once a practitioner is sufficiently trained in interpreting the results, strength, and applicability of the evidence, it is often as simple as that practitioner reading a relevant article in a journal or seeing a conference presentation, conducting a brief literature search related to the article, and then making an informed decision or writing a justification using evidence. Examples of research that have been successfully applied to clinical practice follow, and many are based on nothing more systematic than several individual practitioners being active consumers of the literature and applying the principles of EBP.

CONVERTING RESEARCH TO PRACTICE

The effectiveness of EBP relies on both the availability of research and the ability of practitioners to use it appropriately. If the majority of evidence in P&O is applied research, the results should be readily applicable to everyday practice. Indeed, in some notable instances, clinically applicable research has effected change in clinical practice. Some examples follow, and a subset is listed in the **Table**, with additional descriptions of study design based on a study design-classification scale by Weaver et al. [15] and the source of funding for the research, if listed in the article. Note also that the clinical impact listed for these studies has been observed anecdotally but not documented systematically. Such systematic observation of the effects of research on clinical practice would be an important future step for the field.

In some instances, research follows the concept of EBP by gathering evidence about a certain treatment to measure its effectiveness and, if necessary, refine it. Lonstein and Carlson reviewed the 727 cases of patients with idiopathic scoliosis to assess curve progression [16]. Their results identified the most important indicators, and the article presented several nomograms suitable for use in clinical practice. Some practices that had been orthotically treating patients with small initial curvatures realized, based on the research, which of these patients would likely not have progressed.

Some clinically applicable research alters patient interaction. When research indicated a particular sensitivity of children with spina bifida to latex [17–18], clinical practice was altered through a change in personal protective equipment used by practitioners working with this and other sensitive populations. Geil has assessed the measurement of residual limb shape in persons with limb loss and concluded that certain instruments often used in clinical practice, in particular one model of the VAPC prosthetic caliper, are lacking in accuracy and reliability [19]. Some practices have communicated that they have reevaluated measurement techniques as a result.

A natural means for research to affect clinical practice is through the development of new components and technologies. This avenue might be more routinely exploited; however, a relative lack of funding for research in P&O results in a preponderance of manufacturer-based developments that largely go unpublished. Nonetheless, the development of certain components has been chronicled in the literature, and it is likely that each publication informed and improved that development. The concept of a stance-control orthotic knee was characterized as far back as 1918 by F. H. Windler in Germany. Concepts appeared in thesis work from the 1970s [20–21], previous design iterations were published by National Aeronautics and Space Administration developers [22], a call for additional development was reported in 1994 [23–24], and design iterations were chronicled by Kaufman et al. [25] and McMillan et al. [26]. Pioneering work by Dudley Childress on synergetic prehension [27] led to the development of multiple upper-limb prosthetic devices, including the Hosmer Synergetic Prehensor and the Otto Bock Electrohand for Children. One of the earliest so-called energy-storing prosthetic foot designs was described in 1986 by Hittenberger [28]. Multiple designs that developed in parallel or followed included the Seattle Foot's solid-ankle cushion-heel, deformable forefoot keel concept [29].

EBP in P&O relies on a progression of stages of research, oftentimes from the publication of an initial concept or idea to independent evaluation of that concept. The design of a prosthetic socket is more of a clinical technique than a component that is available in the marketplace, so the literature plays a vital role in dissemination and acceptance of new designs [30–34].

Once a design has been established, impartial evidence concerning effectiveness can inform future practice. Using the contoured adducted trochanteric-controlled alignment method (CAT-CAM) socket as an example, Flandry et al. assessed subjective acceptance, gait deviations, and indicators of fit in five subjects who were switched from quadrilateral sockets to CAT-CAM sockets [35]. The limited number of subjects in this study is common in prosthetics research, and fortunately additional

Table.

Published research in prosthetics and orthotics that has influenced clinical practice. Funding sources include U.S. National Institutes of Health (NIH), Department of Veterans Affairs (VA), and National Institute on Disability and Rehabilitation Research (NIDRR).

Author(s)	Topic	Year	Funding Source	Type of Evidence [1]	Application
Lonstein and Carlson [2]	Idiopathic scoliosis	1984	Internal hospital support and Twin Cities Scoliosis Fund	Case series	Changes in treatment plans for patients with small initial curvatures
Slater [3]	Latex sensitivity	1989	None acknowledged	Controlled trial	Changes in practitioner personal protective equipment use with certain populations
Geil [4]	Prosthetic measurement accuracy	2005	Internal university support	Cross-sectional study	Increased scrutiny of VAPC caliper accuracy and reliability
Kaufman et al. [5]	Stance-control knee orthosis	1996	NIH	Case study	Contributed to design iterations for stance-control knee orthoses
McMillan et al. [6]		2004	None acknowledged/ manufacturer is coauthor	Controlled before-and-after trial	
Childress [7]	Powered grasp	1973	None acknowledged	Description of device design	Development of upper-limb prostheses
Hittenberger [8]	Prosthetic foot design	1986	VA	Description of device design	Development of dynamic elastic response prosthetic feet
Flandry et al. [9]	Transfemoral prosthetic sockets	1989	None acknowledged	Controlled before-and-after trial	CAT-CAM socket-design outcomes and alignment documentation
Gard and Childress [10]	Normal human walking	2001	NIDRR	Cross-sectional study	Challenge to classic concept of six determinants of gait
Kerrigan et al. [11]		2000	NIH, Ellison Foundation	Cross-sectional study	

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CAT-CAM = contoured adducted trochanteric-controlled alignment method.

studies followed to build the evidence [36–38]. While highly regarded levels of evidence such as double-blind randomized controlled trials are rare in P&O, a wide body of smaller studies with lesser controls can still assist clinicians with decision-making and justification for individual patient care.

In other instances, science might alter a widely held clinical opinion, even when that opinion was based on prior publications. Gard and Childress [39–41], as well as Kerrigan and colleagues [42–43], have in the last decade questioned a set of widely taught gait markers, the six "determinants" of normal gait, first published by Saunders et al. in 1953 [44]. The six determinants were theorized without the support of kinematic data but still taught as important markers of normal gait until these researchers began to question the contributions of phenomena such as pelvic obliquity and stance-phase knee flexion on the vertical displacement of the whole-body center of mass, producing data that contradicted prior assumptions. Current research by Geil et al. is focused on challenging a long-held treatment protocol in children with limb loss who require a prosthetic knee for ambulation. Children have been found to use an articulating prosthetic knee effectively in both crawling and walking [45–47] at ages several years younger than conventional treatment would fit them with a knee [48].

While several examples exist of research that has effected change in clinical practice, to the author's knowledge no systematic effort to determine the history of conversion of research to practice has been attempted. Likewise, while this review addresses research that has been applied in practice, it has not attempted to assess whether or not these changes have actually improved practice.

FUTURE RESEARCH NEEDS AND CONCLUSIONS

The implementation of EBP presupposes the need for ongoing research that is clinically applicable. Prosthetists and orthotists can often recognize areas in which research is either nonexistent or immature, more basic than applied, or lacking in external validity. A recent publication detailed the results of a meeting intended to "critically assess the status of research and explore new directions in the field of prosthetics and orthotics" [49]. Participants identified research needs by discipline (prosthetics or orthotics by anatomical region or specialty), and results were presented accordingly. However, the results can be categorized into three general themes that spanned disciplines. Though results were not strictly prioritized, the majority of identified needs related to the first theme: component development. Specific examples included improved prosthetic feet and ankles, especially pediatric feet; weight reduction in upper-limb prostheses and greater variety of components; improved control and efficiency of upper-limb prostheses; and better fabrication of orthoses. These results are interesting, since very little published research in P&O deals with component development and such development is often left to the manufacturers. Researchers investigating component improvement may benefit from a review of efforts to improve prostheses for the developing world [50]. Often, this work is documented and published more readily since it is not manufacturer-driven. Outcomes in this research theme include performance in component-specific tasks, such as validated timed-walking tests [51], and tests of upper-limb motion, such as the box-and-blocks test [52].

A second theme considered research needs in clinical care and management. Specific examples included timing of orthotic management, functional evaluation and classification of lower-limb prosthetic limbs, and the appropriateness of spinal orthotic and surgical prescription. This research is challenging because it often requires longitudinal studies that follow the effects of clinical interventions in several individuals over time. In addition, large numbers of subjects are required to obtain the significance and generalizability necessary to change clinical-care protocols. Fortunately, validated outcomes exist that can be used during these studies [8].

The third theme was more basic and related to better understanding of components and function. Examples called for research leading to better understanding of prosthetic knees, socket suspension, ankle-foot alignment and interaction, use and efficacy of ankle-foot orthoses, effect of lower-limb orthoses on joint alignment, and prevention of falls and foot deformities. These are topics that clinicians often bring to researchers that could potentially improve practice but lack focus and are therefore rarely studied.

A challenge for researchers is the breadth of each of these topics. Research becomes more straightforward when it is based on a few focused, testable hypotheses. Research "into the use and efficacy of AFOs [ankle-foot orthoses]" needs a good deal more detail in terms of focused, testable hypotheses to be effective, which means a substantial number of research efforts will be required to build such broad understanding. At the same time it appears true that, for a variety of reasons, P&O practitioners will not conduct this research. A 2005 online survey of clinicians, conducted by Northwestern University's Rehabilitation Engineering Research Center in Prosthetics and Orthotics, revealed that although 98 percent of respondents regarded research as important, few felt capable of conducting it [49]. More than 78 percent reported that they have identified areas in which further research is needed but lack the ability and resources to carry out the work.

Although a majority of respondents indicated a belief that both the amount of research and the current emphasis on P&O research were lacking, a request to identify the most important problem areas in which research is lacking suggests a growing awareness of the need for EBP. In both prosthetics and orthotics, the highest-ranked area was outcome measures [49]. In response to an open-ended question on future research needs, the topic listed as most important was "Outcome Measures—Efficacy of P&O Service, Evidence-Based Practice" [49].

These data suggest an interesting dichotomy in P&O. Practitioners sense a need for outcomes research and EBP, perhaps because of financial stressors associated with reimbursement but also because of growing dissemination of the principles of EBP [53–55]. Many practitioners also have specific ideas about what research should be done. Nevertheless, the same practitioners are not the ones conducting the research. The reasons for this disparity are many. Because of the evolving educational models in P&O, many practitioners do not have adequate training in conducting even a small research project. Those who do have training find a lack of time and resources to be a major impediment.

The solution is twofold. Practitioners must become consumers of published research results on an ongoing basis. Existing and future practitioners should be trained in developing appropriate questions, searching the literature, reading and interpreting articles, and applying the evidence in practice. Concomitantly, researchers should be cognizant of the needs for evidence as identified by practitioners. Researchers who have the training to produce clinically applicable investigations often lack funding, so funding agencies should be made aware of the need for EBP in P&O. Funding for research in P&O is scarce, particularly in comparison to larger healthcare issues. A review of the Computer Retrieval of Information on Scientific Projects (CRISP) database of projects funded by the U.S. National Institutes of Health (NIH) at the time of the writing of this article demonstrates the Federal funding challenges. A search for new projects including variations of the word prosthetics returned 56 grants. Of those, only 10 concerned limb prosthetics, with only 1 R01 award. The topics of those 10 NIH-funded projects may give some indication of funding trends. Half of the grants focus on neural integration for control of a prosthesis or sensory feedback. Two seek to develop powered prosthetic components. One addresses osseointegration, and the remaining two are not research grants but are instead focused on P&O education and a conference related to functional outcomes. Many of these funded projects are closer to the basic end of the research spectrum and may be far removed from immediate clinical application.

A final example may characterize the current state of clinically applicable research. Vrieling et al. recently published results on gait termination in persons with lower limb loss [56]. The results are clinically applicable and have implications on both gait training and prosthesis design. However, few prosthetists are likely to ever read the article for several reasons. First, because research-need categories are so broad, few would think to search for articles on a topic as specific as gait termination. Second, the journal in which the article is published, *Gait and Posture*, is not a P&O-specific journal and would not be accessible, at least in print, in the vast majority of clinical facilities. The article does appear in online searches for gait termination, and the complete article is available for $30, but few practitioners would make such a purchase based only on the abstract and on such a specific topic. This example illustrates another paradox: general research is requested but difficult because of population size, threats to validity, and breadth of hypotheses; specific research is often better but ignored.

The culture of research in P&O is growing. EBP is being taught and embraced by an increasing number of practitioners, and the research supplying the evidence is by nature accumulative. However, boundaries exist. A divide remains between research producers and research consumers, and the clinically applicable research that is being produced often fails to meet the expectations of those who wish to apply it as part of the evidence to justify patient care.

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